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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0296]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the proposed collection of information by (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written comments on the proposed collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products; Availability

I. Description

FDA is issuing a draft guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of the Prescription Drug User Fee Act (PDUFA) products. The draft guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The draft guidance provides information on how the agency will interpret and apply section 119(a) of the FDA Modernization Act of 1997 (the Modernization Act) (Public Law 105–115). Specific PDUFA goals for the management associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The draft guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at § 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in support of a request for an end-of-Phase 2 meeting and a pre-new drug application (NDA) meeting. The information collection provisions of § 312.47 have been approved by OMB (OMB Control No. 0910–0014). However, the draft guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is providing revised estimates in this notice.

II. Request for a Meeting

Under the draft guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) and and the Center for Biologics Evaluation and Research (CBER) should submit a meeting request to the appropriate FDA component as an amendment to the underlying application.

FDA regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)) state that information provided to the agency as part of an investigational new drug application (IND), NDA, or biologics license application (BLA) must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under IND's and Form FDA 356h must accompany submissions under NDA's and BLA's. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB Control No. 0910–0014, expires December 31, 1999; and FDA Form 356h, OMB Control No. 0910–0338, expires April 30, 2000.

In the draft guidance, CDER and CBER ask that a request for a formal meeting be submitted as an amendment to the application for the underlying product under the requirements of §§ 312.23, 314.50, and 601.2; therefore, requests should be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted in this manner for two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking data bases. Use of the information in the agency's tracking data bases enables the agency to monitor progress on the activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

Under the draft guidance, the agency requests that sponsors and applicants include in meeting requests certain information about the proposed meeting. Such information includes:

- Information identifying and describing the product,
- The type of meeting being requested,
- A brief statement of the purpose of the meeting,
- A list of objectives and expected outcomes from the meeting,
- A preliminary proposed agenda,
- A draft list of questions to be raised at the meeting,
- A list of individuals who will represent the sponsor or applicant at the meeting,

- A list of agency staff requested to be in attendance,
- The approximate date that the information package will be sent to the agency, and
- Suggested dates and times for the meeting.

This information will be used by the agency to determine the utility of the meeting, to identify agency staff necessary to discuss proposed agenda items, and to schedule the meeting.

III. Information Package

A sponsor or applicant submitting an information package to the agency in advance of a formal meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or agency. The agency recommends that information packages generally include:

- Identifying information about the underlying product;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes of the meeting;
- A proposed agenda for the meeting;
- A list of specific questions to be addressed at the meeting;
- A summary of clinical data that will be discussed (as appropriate);
- A summary of preclinical data that will be discussed (as appropriate); and
- Chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The purpose of the information package is to provide agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. Although FDA reviews similar information in the meeting request, the information package should provide updated data that reflect the most current and accurate information available to the sponsor or applicant. The agency finds that reviewing such information is critical to achieving a productive meeting.

The proposed collection of information described in the draft guidance reflects the current and past practice of sponsors and applicants to submit meeting requests as amendments to IND's,

NDA's, and BLA's and to submit background information prior to a scheduled meeting. Agency regulations currently permit such requests and recommend the submission of an information package before an end-of-Phase 2 meeting (§ 312.47(b)(1)(ii) and (b)(1)(iv)) and a pre-NDA meeting (§ 312.47(b)(2)).

Description of Respondent: A sponsor or applicant for a drug or biologic product who requests a formal meeting with the agency regarding the development and review of a PDUFA product.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for the submission of meeting requests and information packages under the draft guidance.

Request for a Formal Meeting: Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that in fiscal year (FY) 1998, 548 sponsors and applicants (respondents) requested formal meetings with CDER and 495 respondents requested formal meetings with CBER regarding the development and review of a PDUFA product. FDA anticipates that the potential number of respondents submitting meeting requests will remain the same, and therefore estimates that the total number of respondents will be 1,043. The agency further estimates that the total annual responses, i.e., the total number of meetings requested per year, will be 1,043, based on data collected from the offices within CDER and CBER. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted with a meeting request in accordance with the draft guidance, is estimated to be approximately 10 hours. Based on FDA's experience, the agency expects it will take respondents this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting. Therefore, the agency estimates that sponsors will use 10,430 hours per year requesting formal meetings with CDER and CBER regarding the development and review of PDUFA products.

Information Package: Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that in FY 1998, CDER held 527 formal meetings and CBER held 415 formal meetings regarding the review of human drug applications as defined in section

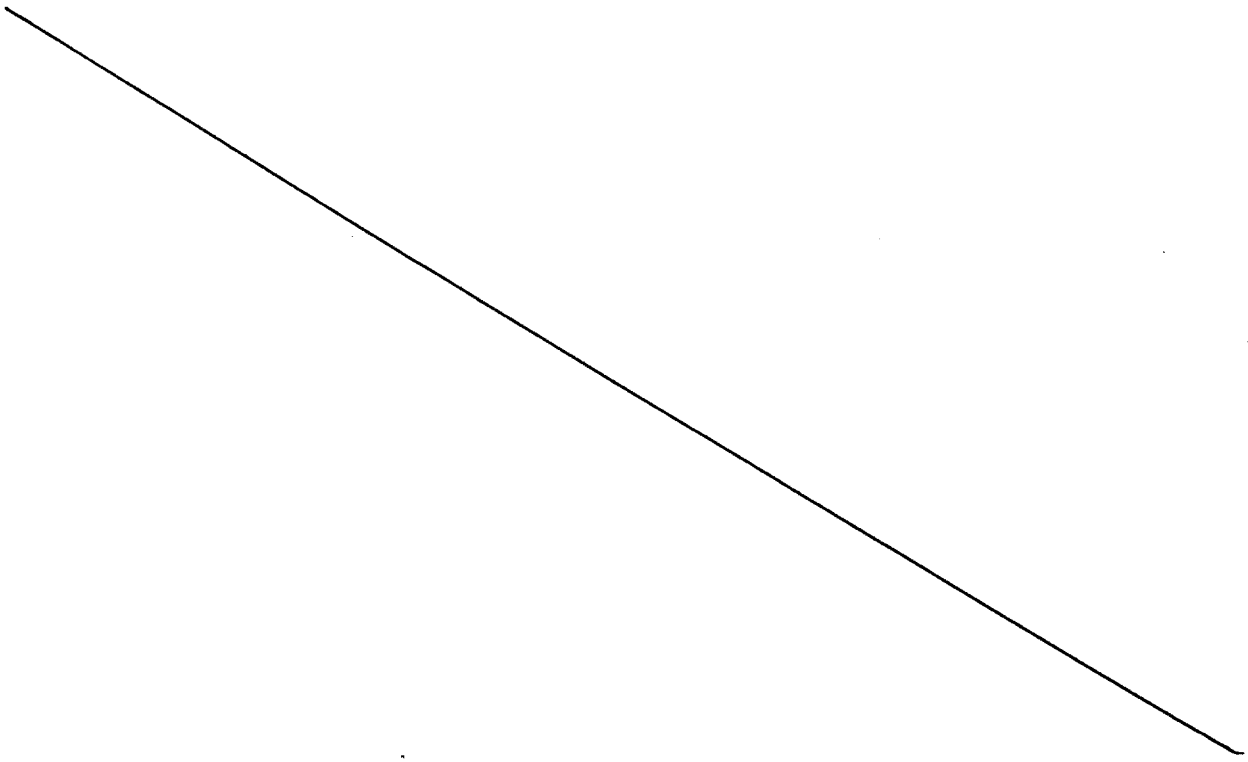
735(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379g). FDA anticipates that the potential number of meetings will remain the same; thus, the agency estimates that total annual responses will be 942. As stated previously, it is the current practice for sponsors and applicants to submit information packages to the agency in advance of any such meeting. In FY 1998, 527 respondents submitted information packages to CDER and 415 respondents submitted information packages to CBER prior to the scheduled meetings. FDA anticipates that the potential number of respondents submitting an information package will remain the same; thus, the agency estimates that the total number of respondents will be 942. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package in accordance with this draft guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the agency expects it will take respondents this amount of time to gather and copy brief statements about the product, a description of the details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the agency. Therefore, the agency estimates that respondents will spend 16,856 hours per year submitting information packages to the agency prior to a formal meeting regarding the development and review of a PDUFA product.

As stated earlier, the draft guidance provides information on how the agency will interpret and apply section 119(a) of the Modernization Act, specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82). The information collection provisions in § 312.47 concerning end-of-Phase 2 meetings and pre-NDA meetings have been approved by OMB (OMB Control No. 0910–0014). These estimates provide for 100 respondents submitting 100 total annual responses at 24 hours per response, equalling 2,400 total burden hours. Therefore, FDA is subtracting these estimates from the estimates described previously for all formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. Specifically, the agency is subtracting in Table

1 of this document burden estimates for meeting requests and information packages for end-of-Phase 2 meetings and pre-NDA meetings. This reduces the total estimated burden hours from 27,386 to 24,986.

In the **Federal Register** of March 19, 1999 (64 FR 13591), FDA invited comments regarding the agency's estimate of the paperwork burden. One comment was received. The comment stated that FDA's estimate is a relatively accurate accounting of time used in administrative preparation of information for routine meetings. The comment stated that FDA underestimated the time required for creative writing and editing tasks associated with preparation of paperwork prior to a formal meeting where many issues or complicated topics will be discussed.

The agency's estimates are based in part on the expectation that respondents will have already compiled for submission to the agency most of the data and information that is described in the guidance document. The agency anticipates that respondents will have submitted the information as part of the underlying product application. Therefore, the bulk of the paperwork burden is related to administrative tasks, i.e., gathering and copying brief statements about the product and describing details of the anticipated meeting.



FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Meeting Request and Information Package	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Meeting Request					
CDER	548	1	548	10	5,480
CBER	495	1	495	10	4,950
Total					10,430
Information Packages					
CDER	527	1	527	18	9,486
CBER	415	1	415	18	7,470
Total					16,956
Subtotal					27,386
Less 2,400 hours					24,986
Total					24,986

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Dated: August 19, 1999

William K. Hubbard
Senior Associate Commissioner for Policy, Planning and Legislation

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